

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

CELSIS IN VITRO, INC.
a Maryland Corporation,

Plaintiff,

v.

CELLZDIRECT, INC., a Delaware Corporation
and wholly-owned subsidiary of INVITROGEN
CORPORATION; and INVITROGEN
CORPORATION, a Delaware Corporation.

Defendants.

Case No. 10-cv-4053

Judge Milton I. Shadur

Magistrate Judge Martin C. Ashman

**RESPONSE TO DEFENDANTS' POST-HEARING BRIEF AND OPPOSITION TO
MOTION FOR STAY OF THE PRELIMINARY INJUNCTION PENDING APPEAL**

Raising a rhetorical white flag, Defendants' Post Hearing Brief practically predicts that this Court will grant the requested injunction. Then, foreshadowing their intention to appeal that decision, Defendants' Post Hearing Brief raises new issues that were not previously before this Court during the preliminary injunction proceedings. To address those new issues Celsis IVT must assume that this Court will enter an injunction, and accordingly, submits this Response and Opposition to the Defendants' Post Hearing Brief.

**I. THE COURT SHOULD NOT STAY EITHER THE PRELIMINARY
INJUNCTION PENDING APPEAL OR THIS LITIGATION.**

Assuming this Court enters a preliminary injunction here, the Defendants have failed to make the requisite showing for this Court to stay the preliminary injunction pending appeal. To warrant such relief under Fed. R. Civ. Pro. 62(c), the Defendants must show that (1) they have made a strong showing that they will likely succeed on the merits of their appeal; (2) they will be irreparably injured absent a stay; (3) the issuance of the stay will not substantially injure the other parties interested in the proceeding; and (4) the public interest lies in favor of granting a

stay. See Fed. R. Civ. Pro. 62(c); *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987) (explaining standard under Rule 62(c)); and *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990) (applying standard in *Hilton*). Interpreting *Hilton*, the Federal Circuit has explained that these four factors effectively merge: “[i]n considering whether to grant a stay pending appeal, this court assesses movant’s chances for success on appeal and weighs the equities as they affect the parties and the public.” *Standard Havens*, 897 F.2d at 513 (citing *E.I. DuPont De Nemours & Co. v. Phillips Petroleum Co.*, 835 F.2d 277, 278 (Fed. Cir. 1987)). In addressing the propriety of the trial court’s consideration of these issues, the Federal Circuit has explained that “the district court ordinarily should not grant both a preliminary injunction and stay.” *Procter & Gamble Co. v. Kraft Foods Global, Inc.*, 549 F.3d 842, 849 (Fed. Cir. 2008) (applying abuse of discretion standard to review of preliminary injunction decision).

This Court addressed this peculiar procedural question in *Abbott Laboratories v. Sandoz, Inc.*, 500 F. Supp. 2d 846 (N.D. Ill. 2007) (Coar, J.). There, Sandoz requested a stay of a preliminary injunction pending appeal because of apparently conflicting Federal Circuit precedent and the Supreme Court’s *KSR* decision. *Id.* at 849-853. The Court rejected each of Sandoz’s arguments, because the case law did not change the outcome of its preliminary injunction decision and the record did not support Sandoz’s request for a stay. Here, the record provides even less support to the Defendants’ request for a stay pending appeal.

To satisfy the first factor, the Defendants must show that on appeal the Federal Circuit will find that this Court somehow *abused its discretion* in granting the preliminary injunction. *Doran v. Salem Inn*, 422 U.S. 922, 932 (1975); and *Abbott Laboratories v. Sandoz, Inc.*, 544 F.3d 1341, 1345 (Fed. Cir. 2008) (affirming grant of preliminary injunction which was not stayed pending appeal). Setting aside that in any assumed grant of a preliminary injunction this Court will have already found that the Defendants: (a) failed to meet their burden to show that

Celsis IVT has not demonstrated a reasonable probability of success on the merits of infringement; and (b) failed to raise a substantial question of both invalidity and unenforceability, the Defendants have presented no new evidence or argument to support any conclusion that this Court would have abused its discretion. Instead, the Defendants simply state “[a]s explained herein, LTC has a significant probability of success on the merits.”¹ This conclusory accusation restating their case against the preliminary injunction fails to meet this first factor of demonstrating their likely success on appeal.

Second, aside from the self-serving statements of Defendants’ own Director of Product Development and Marketing for LTC, the Defendants have offered no evidence or even opinion testimony to support a determination that Defendants have been and will continue to suffer irreparable harm if enjoined. The Defendants also continue to ignore LTC’s financial backing of CellzDirect and offer no proof that CellzDirect or LTC will be meaningfully impacted by the preliminary injunction. To the contrary, Defendants’ non-infringement design-around efforts are likely to keep CellzDirect employees busy with proof-of-concept, development, implementation, testing, and production for the foreseeable future. And if those design-around efforts are successful, then CellzDirect will be back in business.²

Further, the preliminary injunction should not be a surprise to the Defendants, as they have had ample warnings from which to prepare themselves:

- Defendants knew about the LiverPool™ invention at least as early as March 2008 (JX85);
- Defendants knew about the ‘929 patent since November 2009 (Tr. 112:16-114:18; 134:23-25);
- Defendants knew that Celsis IVT sued XenoTech for patent infringement (JX 82; Tr. 129:17-130:1) and that this market was comprised of only a few players (Tr. 280:9-25); and

¹ Dfs.’ Brief at p. 19. If Defendants had wanted this Court to reconsider its decision to grant the preliminary injunction, then they should have sought reconsideration under either Fed. R. Civ. Pro. 59(e) or 60(b).

² Defendants’ design-around are underway as evidence by their Post-Hearing Brief. *See, e.g.*, Dfs.’ Br. at n. 15-18.

- As early as January 2010, the Defendants considered the possibility that Celsis IVT would sue them for patent infringement resulting in their products being taken off the market. (Tr. 609:24-610:15).

Yet, Defendants continued their infringing acts until this Court entered a temporary restraining order. (*See, e.g.*, Tr. 131:4-15; 423:7-424:3.) Simply put, the Defendants have made their infringing bed and this Court should be loath to help them avoid sleeping in it.

Third, Defendants have failed to demonstrate that the issuance of a stay will not substantially injure other parties interested in the proceeding. The first party injured would obviously be Celsis IVT. The Defendants completely ignore Ms. Madden's written testimony (JX4; JX5) and Mr. Peterson's opinion testimony (JX3; Tr. 279:22-334:25) regarding irreparable harm to Celsis IVT and this Court's reliance upon his testimony. Instead, Defendants offer the unsupported assertion that "a short stay will not substantially injure Celsis because any alleged short-term harm is compensable monetarily."³ But, again, the Defendants offer no such proof.

Lastly, the public's interest lies in enforcing the valid and enforceable '929 patent against the Defendants. Moreover, the Defendants have made no showing that the Federal Circuit will reverse this Court's assumed finding of validity and enforceability. As for any of LTC's customers who are using pooled cryopreserved human hepatocytes to develop vital and life-saving drugs and therapies for the public, those customers have the option of purchasing from Celsis IVT, XenoTech, or others. (Tr. 578:11-21; 580:9-25.) Accordingly, the Defendants have failed to satisfy their burden under *Hilton* and the Federal Circuit's application of *Hilton*; and thus this Court should deny Defendants' request for a stay pending appeal.

³ Dfs.' Br. at p. 19.

II. THE DEFENDANTS IMPROPERLY SEEK AN ADVISORY OPINION REGARDING THE SCOPE OF THE PRELIMINARY INJUNCTION

A. The Scope of the Injunction Should Prohibit the Sale of Multi-Cryopreserved Hepatocyte Products Produced Before the ‘929 Patent Issued.

Defendants also foreshadow their anticipated design-around strategies by trying to unduly circumscribe this Court’s authority under Fed. R. Civ. Pro. 65(d) to enjoin Defendants from acts falling within the prohibitions of 35 U.S.C. §271 as those statutes incorporate Claims 1 and 10 of the ‘929 patent.⁴ Celsis IVT does not dispute that the preliminary injunction should enjoin those acts which have or would infringe the Claims of the ‘929 patent, because Rule 65(d) requires that such acts be identified. *See* Fed. R. Civ. Pro. 65(d). Of all the issues Defendants raise, the only issue that was even partially placed before this Court is the issue of alleged stock-piles of multi-cryopreserved hepatocyte products ***completely produced*** before the issuance of the ‘929 patent. Even here, Defendants failed to provide even rudimentary evidence from which the existence of early-produced hepatocytes could have been determined. Dr. Li testified that he did not know when APS’s production prior to June 2010 occurred or whether any vials remained from even that immediately prior production. (Tr. 429:16-19; 430:3-11.) Mr. Hunkeler’s testimony added nothing in this regard. (Tr. 595:1-600:14.) Finally, the Defendants have failed to produce any documents from which this information could be determined.

Even assuming Defendants have some multi-cryopreserved hepatocyte products made before the ‘929 patent issued, Defendants would still be selling those products post-patent issuance. Those multi-cryopreserved hepatocyte products have been proven to be substantial components in Defendants’ customers performance of *in vitro* drug metabolism studies. These studies infringe Claim 10 of the ‘929 patent if Defendants’ products are used. Moreover, Defendants have proven no reasonable non-infringing uses. Consequently, the present sales of

⁴ Dfs.’ Br. at p. 17.

multi-cryopreserved hepatocyte products sold during the term of the '929 patent would contributorily infringe Claim 10 and are squarely within the boundaries of an injunction.⁵ In addition, Defendants ignore that their use of these products in performing their own *in vitro* drug metabolism studies directly infringes Claim 10 under 35 U.S.C. §271(a). Nothing in *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1359-1360 (Fed. Cir. 2007) or *Mycogen Plant Science, Inc. v. Monsanto Co.*, 252 F.3d 1306, 1317-1319 (Fed. Cir. 2001) address infringement under 35 U.S.C. §§ 271(b) and (c). So Defendants' temporal injunction scope concern misses the impact of Defendants' own violation of Claim 10 and its customers' primary infringing use of their products and, thus, should be ignored.

Furthermore, contrary to Defendants' understanding, neither *Monsanto* nor *Mycogen* considered the impact of available remedies under 35 U.S.C. §154(d) for infringement.⁶ Section 154(d) permits this Court to assess a reasonable royalty against an infringer who had actual notice of the published patent application "[i]n addition to other rights provided by this section" 35 U.S.C. §154(d)(1). No court, including *Monsanto* and *Mycogen*, has passed on whether those "other rights" include the right to injunctive relief under 35 U.S.C. §283. Section 154(d)(1) was enacted by Congress to address the concerns of small inventors that large corporations could use the published patent applications (newly-created by the same bill) before patent issuance with absolute impunity. That same published patent application provides direct access into the Patent Office's web portal ("Public PAIR"), which can provide competitors 1-3 months advance notice before any patent issuance. Thus, in anticipation of impending patent issuances, large corporations could stockpile products produced by soon-to-be patented methods. Were it not for the potential application of 35 U.S.C. § 154(d) and its incorporation of injunctive

⁵ In the interest of stream-lining issues for the preliminary injunction hearing, Celsis IVT did not brief the issue of Defendants' inducement of Claim 10 of the '929 patent. However, the Defendants would likely be prohibited from selling pre-issuance products under 35 U.S.C. §271(b) as well.

⁶ Dfs.' Br. at p. 18 n. 14.

relief under 35 U.S.C. §283, *Monsanto* and *Mycogen* could be read to preclude the application of 35 U.S.C. §271(g) to such willful pre-patent issuance stockpiling. There is no indication that the Federal Circuit reached—let alone even contemplated—this narrow, yet important issue.

B. Defendants Improperly Seek An Advisory Opinion to Aid Their Efforts to Design-Around the ‘929 Patent.

In an effort to persuade this Court to narrowly-tailor the preliminary injunction, Defendants rely upon unsupported attorney arguments and several isolated comments of Dr. Strom to import unrecited process steps and various techniques into Claims 1 and 10 of the ‘929 patent.⁷ Essentially, what Defendants are asking from this Court is an advisory opinion regarding a hypothetical design-around process without presenting any evidence as to what that process actually is. Had Defendants presented such evidence, then Celsis IVT may have presented alternative direct infringement theories or theories under the doctrine of equivalents.

Defendants’ first effort to create a hypothetical process is to restrict the preliminary injunction by importing “twice frozen and twice thawed” limitations into Claims 1 and 10.⁸ Defendants offer no evidence that a person of ordinary skill in the art in April 2005 would have interpreted the ‘929 patent by importing a “second thaw step” into the Claims. A second thaw step is not recited in either Claim 1 or 10 (JX1). Moreover, whether a limitation is present in a claim is solely a question of law for this Court—not a question for a technical expert like Dr. Strom.⁹

Defendants next seek to carve-out hypothetical techniques, including “elutriation” and “plastic adherence”, for performing the density gradient fractionation step “on the basis of any

⁷ Dfs.’ Br. at p. 18 and n. 16-18.

⁸ Dfs.’ Br. at p. 18 n. 15.

⁹ Defendants misrepresent Dr. Strom’s testimony in this regard. At the portion of the transcript cited by the Defendants, when read in context, Dr. Strom merely testified that to test viability one needs to thaw the hepatocytes. (See Tr. 210:4-15.)

property other than density.”¹⁰ In addition, they read Claim 10 as a dependant claim relying upon Claim 1.¹¹ Yet, Defendants proffer scant evidence as to what those techniques actually are, and no evidence as to how the Defendants would implement these techniques or how those techniques would fit into or out of the ‘929 patent. They also proffer no evidence that a person of ordinary skill in the art in April 2005 would have held any understanding that Claim 10 somehow depends from Claim 1 (which it does not). (*See* JX1.) Moreover, Defendants’ reliance on Dr. Strom’s testimony is misplaced. None of Defendants’ cross-examination questions to Dr. Strom asked his opinion as to how a person of ordinary skill in the art would have understood those techniques as falling within the scope of the ‘929 patent. Other than Dr. Strom, Defendants offer no opinion testimony or any other evidence to support their position.

Further, Defendants seek to fashion another hypothetical design-around step by restricting the “not plated” step in Claims 1 and 10 to exclude plating “for any purpose between the first and second cryopreservations.”¹² Defendants’ reliance upon an isolated statement by Dr. Strom (Tr. 189:6-11) is a narrow reading of his full opinions regarding the interpretation of “plated” as set forth in his Declaration. (*See, e.g.*, JX6 at ¶¶ 70-74; JX15 at p. 7.) Also the ‘929 patent specification discloses some examples of plating on collagen-coated tissue culture plates or tissue culture plates coated with other extra-cellular matrix proteins and that one purpose of plating is to demonstrate whether the cells attach to the plate. (JX1 at col. 13:25-43.)

Defendants’ final effort to create a hypothetical design-around strategy seeks this Court’s permission to practice a density gradient fractionation step *after* the final thaw to achieve a viability exceeding 70%¹³. Again, Defendants proffer no evidence demonstrating that it does or

¹⁰ Dfs.’ Br. at p. 18 n. 16.

¹¹ Dfs.’ Br. at p. 18 n. 16.

¹² Dfs.’ Br. at p. 18 n. 17.

¹³ Dfs.’ Br. at p. 18 n. 18.

will sell multi-cryopreserved hepatocyte products with viabilities less than 70% or what new thawing instructions it intends to provide to its customers.

Taken together, Defendants' requests are wholly inappropriate as seeking an advisory opinion as to whether a hypothetical design-around method will avoid contempt. Had the Defendants presented evidence of its design-around efforts, instead of musing about a hypothetical process, then Celsis IVT would have likely presented additional direct and equivalent infringement theories.¹⁴ Accordingly, the Defendants are not entitled to an advisory opinion.

III. CELSIS IVT'S PERFORMANCE OF DEFENDANTS' ACCUSED PROCESS IS NOT REQUIRED TO DEMONSTRATE A LIKELIHOOD OF SUCCESS ON THE MERITS OF INFRINGEMENT

The Defendants argue for the first time that Celsis IVT must show that it performed (or directed its expert to perform) Defendants' accused process in order to properly show a likelihood of success on the merits.¹⁵ The authority upon which the Defendants rely does not support the proposition that in the context of a preliminary injunction proceeding, the Federal Circuit requires a patentee to practice the accused method in order to show a likelihood of success of infringement. In fact, none of Defendants' authority even addresses the absence of proof at the preliminary injunction stage or the requirement to practice the accused process. *See, e.g., Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384 (Fed. Cir. 1992) (appeal of summary judgment), *Abbott Laboratories v. Baxter Healthcare Corp.*, 660 F. Supp. 2d 882 (N.D. Ill. 2009) (summary judgment); and *In re Omeprazole Patent Litigation*, 490 F. Supp. 2d 381

¹⁴ If the Defendants are genuinely concerned about a future contempt proceeding involving their design-around methods, then Defendants are welcomed to approach Celsis IVT for its review of their design-around methods. Celsis IVT can then make an independent determination as to whether those methods would infringe the '929 patent. Short of that, the Defendants are not entitled to an advisory opinion to avoid future contempt proceedings.

¹⁵ Dfs.' Br. at p. 1-2.

(S.D.N.Y. 2007). Accordingly, Defendants' new position is simply more unsupported attorney argument and should be rejected.

IV. CONCLUSION

For the reasons discussed above, assuming this Court enters the preliminary injunction, this Court should deny the Defendants' request to stay the preliminary injunction pending appeal, reject Defendants' newly-raised arguments, and grant whatever further relief is appropriate under the circumstances.

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CERTIFICATE OF SERVICE

I, Adam G. Kelly, certify that a copy of the foregoing **RESPONSE TO DEFENDANTS' POST-HEARING BRIEF AND OPPOSITION TO MOTION FOR STAY OF THE PRELIMINARY INJUNCTION PENDING APPEAL** was served via ECF filing upon the following on the 26th day of August, 2010:

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